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IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

In re PATENT APPLICATION OF

Mitchell E. REFF et al.

Group Art Unit: 1644

Application Serial No. 09/292,053

Examiner: Phuong N. Huynh

Filed: April 14, 1999

Title: GAMMA-1 ANTI-HUMAN CD23 MONOCLONAL ANTIBODIES AND USE THEREOF AS THERAPEUTICS

June 16, 2003

* * * * *

REMARKS ACCOMPANYING A REQUEST FOR CONTINUED EXAMINATION PURSUANT TO 37 C.F.R. § 1.114

Mail Stop RCE
Commissioner for Patents
P.O. Box 1450
Alexandria, VA 22313-1450

Sir:

This is submitted in accompaniment to a Request for Continued Examination pursuant to 37 C.F.R. § 1.114, and in response to the Advisory Action dated June 4, 2003. The applicants traverse the averment in the Advisory Action that the amendment filed on May 14, 2003 contains new matter, and respectfully request entry of the amendment prior to continued examination on the merits.

The Advisory Action states that:

> "The proposed amendments to claims 38, 46, and 47, and newly added claims 55-62 raises the issue of new matter because the specific nucleotides '124-165, 211-231, and 328-357' of SEQ ID NO. 1, '148-165, 208-258, and 355-390' of SEQ ID NO. 3, '136-168, 214-234, and 331-357' of SEQ ID NO. 5, and '148-168, 211-261, and 358-378' of SEQ ID NO. 7 have no support in the claims and the specification as originally filed."

The objected-to nucleotide sequences recited in claims 38, 46, and 47 are not new matter, because they are expressly disclosed and described on pages 50-52, 54-56, 59-60, and

62-63 of the specification as the nucleotide sequences encoding the complementarity-determining regions CDR1, CDR2, and CDR3 of the light and heavy chains of antibodies 6G5 (SEQ ID NOs. 1 and 3) and 5E8 (SEQ ID NOs. 5 and 7). Humanized antibodies produced by CDR grafting are disclosed on page 13, line 3.

Newly added claims 55 and 60 are directed to the disclosed method wherein the antibody that is administered comprises the variable regions of the light and heavy chains of antibodies 6G5 shown as amino acids 1-111 of SEQ ID NO: 2 and amino acids 1-122 of SEQ ID NO: 4, respectively. Newly added claims 56 and 61 are similarly directed to the disclosed method wherein the antibody that is administered comprises the variable regions of the light and heavy chains of antibodies 5E8 shown as amino acids 1-107 of SEQ ID NO: 6 and amino acids 1-118 SEQ ID NO: 8, respectively. The complete nucleotide sequences of the variable regions of the light and heavy chains of antibodies 6G5 and 5E8 that are recited in these claims are also expressly disclosed and described on pages 50-52, 54-56, 59-60, and 62-63 of the specification, and their insertion into a recombinant DNA vector to produce antibodies having human constant regions is described, for example, on page 46.

The express written description of the nucleotide sequences of claims 38, 46, 47, and 55-62 in the text of the present application is clear evidence that the applicants were in possession of the claimed subject matter at the time the present application was filed, and that the objected-to nucleotide sequences are not new matter. Entry of the amendment is therefore respectfully requested.

Respectfully submitted,

PILLSBURY WINTHROP, LLP

By _____

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RCE/ 1644

IN THE ED STATES PATENT AND TRADEMA OFFICE PATENT APPLICATION

Group Art Unit 1644
Examiner: Phuong N. Huynh

Inventor(s): REFF et al.
Appln. No.: 09/ | 292,053 (Series Code ↑ | Serial No. ↑)
Atty. Dkt. P | 275739 (M#) | 1997-30-0565D1 (Client Ref)

Filed: April 14, 1999
Mail Stop AF
Hon. Commissioner for Patents
PO Box 1450
Alexandria, VA 22313-1450

Appln. Title: Gamma-1 Anti-Human CD23 Monoclonal Antibodies and Use Thereof as Therapeutics

OIPE JC76 JUN 16 2003 PATENT & TRADEMARK OFFICE

RECEIVED JUN 19 2003 TECHNOLOGY CENTER 1600/2900

Sir:

REPLY/AMENDMENT/LETTER

Date: June 16, 2003 = Monday
June 14, 2003 = Saturday

This is a reply/amendment/letter in the above-identified application and includes the herewith attachment of same date and subject which is incorporated hereinto by reference and the signature below is treated as the signature to the attachment in absence of a signature thereto.

FEE REQUIREMENTS FOR CLAIMS AS AMENDED

1. Small Entity claim
A. ☒ NOT made
B. ☐ Withdrawn
C. ☐ made herewith
D. ☐ made previously
For B & C See Required Separate Paper (Pat-256)

	Claims remaining after amendment	Highest number previously paid for		Present Extra	Large/Small Entity	Additional Fee	Fee Code Lg/Sm
2. Total Effective Claims	24	**minus	37	0	x $18/$9 =	+ $0	103/203
3. Independent Claims	2	***minus	3	0	x $84/$42 =	+ $0	102/202
4. If amendment enters proper multiple dependent claim(s) into this application for first time (leave blank if this is a reissue application) ..... add					+ $280/$140 =	+ $0	104/204
5. Original due Date: April 14, 2003		☐ NONE					
6. **Petition is hereby made** to extend the original due date to cover the date this response is filed for which the requisite fee is attached			(1 mo) (2 mos) (3 mos) (4 mos) (5 mos)	$110/$55 = $410/$205 = $930/$465 = $1,450/$725= $1,970/$985=	+ $410		115/215 116/216 117/217 118/218 128/228
7. Enter any previous extension fee paid since above original due date and subtract					- $110		
8.					**Extension Fee**	+ $300	
9. If **Terminal Disclaimer** attached, add Rule 20(d) official fee					+ $110/$55	+ $0	148/248
10. If IDS attached requires Official Fee under Rule 97 (c), ... add or if Rule 97(d) Request ..... add					+ $180 + $180	+ $0	126 126
11. After-Final Request Fee per rules 129(a) and 17(r)					+ $750/370	+ $0	146/246
12. No. of additional inventions for examination per Rule 129(b).....					x $750/375 ea	+ $0	149/249
13. Request for Continued Examination (RCE)					+ $750/375	+ $750	1179/1279
14. Petition fee for						+ $0	
15.					**TOTAL FEE =**	**$1050**	

16. *If the entry in this space is less than entry in next space, the "Present Extra" result is "0".
17. **If the "Highest number previously paid for" in this space is less than 20, write "20" in this space.
18. ***If the "Highest number previously paid for" in this space is less than 3, write "3" in this space.

PLEASE CHARGE OUR DEP. ACCT

Our Deposit Account No. 03-3975)
(Our Order No. 37003 (C#) | 275739 (M#))

CHARGE STATEMENT: The Commissioner is hereby authorized to charge any fee specifically authorized hereafter, or any missing or insufficient fee(s) filed, or asserted to be filed, or which should have been filed herewith or concerning any paper filed hereafter, and which may be required under Rules 16-18 (missing or insufficiencies only) now or hereafter relative to this application and the resulting Official Document under Rule 20, or credit any overpayment, to our Accounting/Order Nos. shown above, for which purpose a duplicate copy of this sheet is attached.
This CHARGE STATEMENT does not authorize charge of the issue fee until/unless an issue fee transmittal sheet is filed.

Query: Is appeal deadline now? If so, file Notice of Appeals separately.

Pillsbury Winthrop LLP
Intellectual Property Group
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Atty/Sec: TAC/ksh